

## **REMARKS**

### **Status**

Claims 1-14 and 18-42 are currently pending in the application. The present amendment does not add or cancel any claims. Accordingly, it is claims 1-14 and 18-42 which are at issue.

### **The Rejection**

Claims 1-14 and 18-42 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 1-5, 8-9, 13-14, 20-23, 26, 31-32, 34-35 and 42 were rejected under 35 U.S.C. §102(b) as being anticipated by Shaw et al. (US 5,678,572). Claims 7, 19, 24-25, 27, 31 and 36-41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shaw et al. Claims 10, 12 and 33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shaw et al. in view of Bonutti (US 5,454,365). Claims 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shaw et al. in view of Adams et al. (US 5,325,848). Finally, claims 28-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shaw et al. in view of Nobles et al. (US 2002/0013601).

### **Remarks Directed to the Rejection of Claims 1-14 and 18-42 under 35 U.S.C. §112, Second Paragraph**

Regarding independent claim 1, this claim recites a medical device having a guide member with an aperture and a pair of expansion arms adapted to extend along respective edge regions of the aperture. Applicant respectfully submits that the term "edge regions" is not preceded by the term "the" or "said" and as such requires no antecedent basis. In addition, Applicant submits that the term "edge regions" of the aperture is self-explanatory from the specification and the drawings, and thus no formal definition in the specification is required

given that one skilled in the art would know that the edge regions correspond to the edge of the aperture.

Regarding claim 34, the same comments and/or arguments above for claim 1 also apply for this claim.

Regarding claim 6, this claim has been amended such that it is clear that there is a first stressed position and a further stressed position.

Regarding claim 25, this claim has been amended to depend on claim 24.

In summary, claims 1, 6, 25 and 34 as currently amended are submitted to no longer be indefinite. Therefore, Applicant respectfully requests that the rejection of claims 1-14 and 18-42 under 35 U.S.C. §112, second paragraph, be withdrawn.

**Remarks Directed to the Rejection of the Claims  
under 35 U.S.C. §102(b) and 35 U.S.C. §103(a)**

Applicant respectfully submits that where the Examiner has interpreted the openings between the stays (1, 1') of the embodiment of Figures 4a and 4b as access areas in Shaw et al., the stays (1, 1') clearly do not extend *along* respective edge regions of the same aperture. In addition, the Office Action appears to have interpreted the stays (1, 1'), rather than the flat strips (11"), as serving to define an access area. However, claim 1 clearly states that it is an aperture in the guide member that defines the access area. In contrast, the Office Action has indicated that the flat strips (11") form part of the guide member (2). Were the flat strips (11") to be interpreted as defining an access area, then each opening in Shaw et al. would not comprise a pair of expansion arms, nor could the stays (1 or 1') be interpreted as extending along respective edges of the opening.

Applicant also respectfully submits that the Office Action does not appear to have considered the presence of the flat strips (11''). However, far from being inconsequential, the flat strips (11'') would impede any construed viewing and/or access through the perceived openings between the stays (1, 1'). Furthermore, contact between the flat strips (11'') and the wall of the body passage would distort the expansion of the body passage.

Claim 1 has also been amended to emphasize that the expansion arms are uninterruptedly separated by the access area. Support for this amendment, and some of the advantages of this feature, may be found in the description on at least page 17, lines 13-22, and in Figures 7, 8, 9, 25 and 26. In particular, viewing of the body passage through the access area of the present invention is uninterrupted, aiding diagnosis of any encountered features and aiding access to the features. Additionally, a feature, such as a tumor, can be maintained in the same position relative to the longitudinal axis of the device while the body passage is expanded by the pair of expansion arms, thereby aiding viewing of, and access to, the feature. For example, viewing of a feature while the apparatus is directed towards the feature for observation while the body passage is expanded is afforded. As the position of the feature remains relatively constant during expansion, a viewing position of the apparatus does not require alteration.

In contrast, should the device of Figures 4a and 4b of Shaw et al. be applied to a body passage, with some sort of viewing apparatus directed between the stays (1, 1') and flat strips (11''), the viewing position would need to be altered during expansion of the stays (1, 1') as the contact between the flat strips (11'') and the body passage would maintain a portion of the body passage fixed relative to the longitudinal axis, while the expansion of the stays (1, 1') would pull the feature away from the flat strips (11''). Should the stays (1, 1') of Shaw et al. be expanded to such an extent that contact between the flat strips (11'') would become insufficient to restrict the

movement of the wall of the body passage during expansion, the flat strips (11") would not be supporting the body passage and the body passage would be prone to rupture under the pressure of the stays (1, 1').

Regarding claim 42, the Office Action rejected the claim stating that activating members (12, 12') of Shaw et al. were capable of moving simultaneously. However, claim 42 requires an *activating member configured to move the expansion arms simultaneously*. Clearly neither activating member of Shaw et al., either 12 or 12', is capable of moving multiple stays simultaneously and Applicant respectfully submits that claim 42 is not anticipated by this prior art reference.

Regarding claims 27 and 31, the inflatable element and the flexible cover, respectively, have been found to be obvious on the basis of Shaw et al. The embodiment of Shaw et al. relied upon in the Office Action has an inflatable hollow tube replacing stays 1 and 1'. In contrast, currently amended claims 27 and 31 require all the elements of claim 1 such as the access area spaced from the leading end, in addition to at least one inflatable element (claim 27) and a flexible cover (claim 31). This feature, and other features of claim 1, from which claims 27 and 31 depend, are not present. As such, Applicant respectfully submits that one skilled in the art would not have looked to combine the two embodiments of Shaw, and should one have done so, it is still not apparent how one skilled in the art could have arrived at the apparatus as defined in claims 27 and 31.

Regarding the rejection of claim 10, the screw mechanism of Bonutti causes the distal end of the apparatus to be retracted, thus shortening the aperture. Were one skilled in the art to apply Bonutti to Shaw et al., the result would be an embodiment similar to the embodiment of Figures 1-3d of Shaw et al., with activation of the stays by a screw mechanism. Such an

embodiment would not make obvious the present invention. Shortening the aperture is undesirable in the present invention as it would lead to longitudinal compression of tissue in the body passage.

In summary, Applicant respectfully submits that currently amended claims 1-14 and 18-42 are no longer unpatentable under 35 U.S.C. §102(b) or §103(a). Therefore, Applicant respectfully requests that the rejection of the claims be withdrawn and the claims moved towards allowance.

**Conclusion**

In view of the amendments and remarks presented herein, Applicant respectfully submits that all claims are now in condition for allowance. Any questions, comments, or suggestions the Examiner may have which would place the application in still better condition for allowance should be directed to the undersigned attorney.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1180.

Dated: 9/7/2010

Respectfully submitted,

By Mark A. Harper  
Mark A. Harper, Ph.D.

Registration No.: 60,248  
GIFFORD, KRASS, SPRINKLE, ANDERSON  
& CITKOWSKI, P.C.  
2701 Troy Center Drive, Suite 330  
Post Office Box 7021  
Troy, Michigan 48007-7021  
(248) 647-6000  
(248) 647-5210 (Fax)  
Attorney for Applicant